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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,698	07/26/2005	Yossef Shemer	4787-7000	1830

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EXAMINER	
SZMAL, BRIAN SCOTT	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
05/22/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/531,698	SHEMER ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *39-41* is/are allowed.

6)☒ Claim(s) *1-8,10,12 and 14-38* is/are rejected.

7)☒ Claim(s) *9,11 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 April 2005 and 25 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Drawings

1. The drawings were received on January 25, 2008. These drawings are acceptable.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4-7, 14-18, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakayama et al (5,730,149).

Nakayama et al disclose a toilet mounted urinalysis unit and further disclose a collection and sampling subunit measuring the at leas tone characteristic of urine, the sub-unit including at least one means for measuring the at least one characteristic of urine; an electronics subunit; means for removably fastening the toilet unit, the means extending over the lip of the toilet bowl so that the collection and sampling subunit is positioned inside a toilet bowl, measuring the at least one characteristic of the collected urine, the means operative to permit non-permanent positioning of the toilet unit in any of a plurality of toilet bowls; a first communication link for data transfer between the collection and sampling subunit and the electronics subunit, the first communications link attached to, or embedded in the means for removably fastening; a wall unit having a second communication link for data transfer between the wall unit and the toilet unit, the

wall unit further includes means for storing data, and processing data to determine if changes have occurred in the at least one measured characteristic of urine; a flexible strap; the means for removably fastening is a rigid element positionable on the lip of a toilet; the means for removably fastening is a hook-shaped element (94, 96); a sample cell and a means for measuring conductivity; a plurality of detectors; the collection and sampling subunit, the electronics subunit and the communications link therebetween the toilet unit are integrated into a single unit; the electronics subunit includes a processing unit, a communications link to the wall unit, and a power supply; the power supply (68) is a battery; the wall unit includes a processing unit, a memory, a display, a means for inputting information and a communications link to the toilet unit; the communications link between the wall unit and the toilet unit is a wireless link (Figure 1 does not show a wired connection, therefore it is assumed that the connection is wireless); and the wall unit is detachable, transportable and usable with a plurality of sanitary installations. See Abstract; Figure 1-3, 20; Column 9, lines 46-67; Column 10, lines 1-7; Column 11, lines 34-39; Column 16, lines 14-18 and 30-35; Column 17, lines 43-50; Column 19, lines 54-58 and 65-67; and Column 20, lines 1-2.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 1 above, and further in view of Ackerman (2002/0026111 A1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis but fail to disclose the system further includes an output means operative in response to a change in the measured characteristic of urine, the change being greater than a predetermined threshold value, thereby providing an output indication indicating that the individual requires further examination; and the output means includes an alarm.

Ackerman discloses a means for monitoring glucose concentration in a physiological fluid and further discloses the system further includes an output means operative in response to a change in the measured characteristic of urine, the change being greater than a predetermined threshold value, thereby providing an output indication indicating that the individual requires further examination; and the output means includes an alarm. See Paragraphs 0011, 0022-0024, 0026, 0028, 0082 and 0165-0167.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the use of monitoring the glucose concentration and comparing it to a threshold, as per the teachings of Ackerman, since it is well known to monitor glucose concentrations and compare the measured concentration against a threshold value to determine if the patient requires medical assistance.

6. Claims 8, 19, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 1 above, and further in view of Saito et al (5,119,829).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis utilizing multiple detectors, but fail to disclose a single light source and a plurality of detectors; the communications link between the wall unit and the central computer includes a wired link.

Saito et al disclose a toilet based urinalysis means and further disclose a single light source; the communications link between the wall unit and the central computer includes a wired link. See Column 6, lines 47-49; and Column 15, lines 38-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the use of a light source for analysis, as per the teachings of Saito et al, since it would provide another means of analyzing the urine sample. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a wireless link between the electrical components of the current invention, since it is well known to utilize either a wired or wireless communications link between electrical components. It also would have been obvious to utilize a batter as a power source for the wall unit, since the power source would have to be either a battery or house current.

7. Claims 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) as applied to claim 7 above, and further in view of Hough et al (6,261,522 B1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis, but fail to disclose a plurality of light sources and a plurality of detectors.

Hough et al disclose a spectrophotometric apparatus and further disclose a plurality of light sources (30) and a plurality of detectors (32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include a plurality of light sources and a plurality of light detectors, as per the teachings of Hough et al, since it would provide another means of analyzing the urine sample.

8. Claims 25-29 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) in view of Ackerman (2002/0026111 A1).

Nakayama et al, as discussed above, disclose a toilet based means for urinalysis and further discloses positioning a means for collecting and measuring a characteristic of urine in a toilet bowl; collecting urine; measuring the value of the characteristic of the collected urine while the urine is in the means for collecting and measuring positioned within the toilet bowl; identifying the user; measuring the concentration of at least one constituent of the urine; measuring the amount of at least one constituent of the urine; and measuring the conductivity of the urine. See Abstract; Figure 1-3, 20; Column 9, lines 46-67; Column 10, lines 1-7; Column 11, lines 34-39; Column 16, lines 14-18 and 30-35; Column 17, lines 43-50; Column 19, lines 54-58 and 65-67; and Column 20, lines 1-2.

Nakayama et al however fail to disclose comparing the measured value to a threshold value; indicating the measured value exceeds the threshold value; testing the

reasonableness of the measured characteristic; measuring the pH of the urine; comparing the measured value to a threshold value based on the average of similar measurements over a period of time; the predetermined period of time has changeable start and end dates or fixed start and end dates; and comparing at least two characteristics of the body fluid.

Ackerman, as discussed above, disclose a means for measuring glucose of a body fluid and further disclose comparing the measured value to a threshold value; indicating the measured value exceeds the threshold value; testing the reasonableness of the measured characteristic; measuring the pH of the urine; comparing the measured value to a threshold value based on the average of similar measurements over a period of time; the predetermined period of time has changeable start and end dates or fixed start and end dates; and comparing at least two characteristics of the body fluid. See Paragraphs 0011, 0022-0024, 0026, 0028, 0082 and 0165-0167.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Nakayama et al to include the ability to compare the measured concentration against a threshold value, as per the teachings of Ackerman, since it would provide a means of determining if the patient requires medical assistance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a standard deviation or a percentage as the threshold value, since it is well known to utilize such vales to determine if the measured quantity is an abnormal or normal measurement.

9. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakayama et al (5,730,149) in view of Ackerman (2002/0026111 A1) as applied to claim 25 above, and further in view of Saito et al (5,119,829).

Nakayama et al and Ackerman, as discussed above, disclose means for measuring characteristics of urine, but fail to disclose the measurement of the temperature of the urine.

Saito et al, as discussed above, disclose a toilet based urinalysis means and further disclose measuring the temperature of urine. See Column 9, lines 17-22.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nakayama et al and Saito et al to include the ability to measure the temperature of urine, as per the teachings of Saito et al, since it would provide a means of determining if the patient has an infection or fever.

Allowable Subject Matter

10. Claims 9, 11 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: Claims 39-41 are allowable since they incorporate the claim language of previously objected Claims 9, 11 and 13.

Response to Arguments

12. Applicant's arguments filed January 25, 2008 have been fully considered but they are not persuasive.

The Applicants argue the currently amended claims are not anticipated by Nakayama et al, because Nakayama et al fails to disclose the means for removably fastening the toilet unit extends over the lip of the toilet bowl so that the collection and sampling sub-unit is positioned within the toilet bowl; the measurement is made by the collection and sampling sub-unit when it is positioned within the bowl; the collection and sampling sub-unit includes means for measurement; and the means for fastening is operative to permit non-permanent positioning of the unit. The Examiner respectfully disagrees. Nakayama et al clearly shows a removably fastening means that extends over the lip of the bowl so that the collection and sampling sub-unit is positioned within the bowl (see Column 10, lines 21-27; the T-shaped slot on the underside of the unit is integral with the whole analysis unit, and therefore the removably fastening means extends over the lip of the bowl); the measurement is made by the collection and sampling sub-unit when it is positioned within the bowl (see Figure 8; the sub-unit is clearly positioned within the bowl); the collection and sampling sub-unit includes means for measurement (see Figure 7; electrodes 126 and 128 measure the volume of accumulated urine); and the means for fastening is operative to permit non-permanent positioning of the unit (see Column 10, lines 21-27; the T-shaped slots allow for non-permanent positioning of the unit). Therefore, the rejection of Claims 1, 4-7, 14-18, 21 and 24 is being maintained.

The Applicants also argue Nakayama et al and Ackerman fail to disclose the claimed elements of Claims 25-29 and 31-38, because Nakayama et al fail to disclose the measurement of a value of the at least one characteristic of the collected urine while the urine is in the means for collecting and measuring positioned within the bowl. As discussed above with respect to the Claim 1 arguments, Nakayama et al clearly disclose this claim limitation in Figure 7 and Column 12, lines 5-8. Therefore, the rejection of Claims 25-29 and 31-39 is being maintained.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Patent Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736